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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,152	12/31/2001	Mian-Ying Wang	10209.383	3964

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EXAMINER	
HOFFMAN, SUSAN COE	
ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
03/02/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/036,152	WANG ET AL.	
	Examiner	Art Unit	
	Susan Coe Hoffman	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2005 and 15 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 15, 2004 has been entered.

2. Claims 1-33 are currently pending.

Inventorship

3. In view of the papers filed November 14, 2004, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the addition of Stephen P. Story as an inventor.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 31-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting hepatic carcinogens from causing liver damage, does not reasonably provide enablement for the prevention of liver damage by hepatic carcinogens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are broadly drawn to a method for preventing liver damage caused by hepatic carcinogens. In order to be enabled for prevention of a condition, applicant must demonstrate that the invention is able to prevent the condition in each and every instance of that condition. Applicant's specification does not set forth any evidence that the claimed product is able to prevent liver damage caused by all potential hepatic carcinogens in all potential patients. Thus, since applicant's specification does not show prevention of liver damage in all patients by all potential hepatic carcinogens, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if applicant's invention actually function as claimed. Therefore, the claims are not considered enabled for the prevention of liver damage by hepatic carcinogens.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-22, 25, 26, 28 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 2-22, 25, 26, 28 and 32 recites the limitation "said Morinda citrifolia." The antecedent basis for this limitation is unclear. Each of these claims depends from an independent claim which contains two M. citrifolia components, juice and puree. It is unclear if the phrase "said Morinda citrifolia" is referring to the juice, the puree or both. Clarification is needed.

6. Claims 4 and 5 are indefinite because they formulation is in solid form or powder form. Claim 1 states that the composition contains juice. Juice is a liquid. Thus, it is confusing to require a composition that requires a liquid component to be in a solid form.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 27-33 are rejected under 35 U.S.C. 103(a) as being obvious over Jensen (US 7,018,662).

The applied reference has two common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived

from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

This reference teaches a method for treating or inhibiting hepatocellular carcinomas by administering a composition comprising M. citrifolia juice and puree twice daily. The reference teaches that the composition inhibits COX-2 (see column 2, lines 49-55; column 5, lines 12-14; column 6, lines 51-52 and Example 4 and 5).

The reference does not specifically teach administering the amounts of M. citrifolia claimed by applicant. The dosage of a pharmaceutical ingredient is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The reference specifically teaches that the dose level should be varied by the artisan to suit the patient's age, body weight, health, gender, diet, time of administration, route of administration, rate of excretion, drug combination and the severity of

the particular disease currently being treated (see column 6, lines 28-34). Therefore, an artisan would have been motivated to modify the dosage of the M. citrifolia in order to formulate a regimen that best achieves the desired results set forth in the reference. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of dosage amount would have been obvious at the time of applicant's invention.

The reference does not specifically teach that the inhibition or treatment of hepatocellular carcinoma occurs using the same mechanisms claimed by applicant. However, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

8. Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 08-217686 (translation provided).

JP '686 teaches administering Morinda citrifolia to treat hepatitis and hepatic cancer caused by Helicobacter pylori (see paragraphs 8 and 16 of the translation). The reference does not specifically state that the composition prevents cancerous growth by blocking carcinogen-DNA adduct formation. However, since the reference composition is able to treat the same cancer as that claimed by applicant, the reference composition is considered to have this property.

The reference does not specifically teach administering the amounts of M. citrifolia claimed by applicant. The dosage of a pharmaceutical ingredient is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the

general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The reference teaches administering a wide range of dosage of the M. citrifolia (see paragraph 8 of the translation). By teaches a wide range of dosages, the reference acknowledges that dosage amount can be varied. Therefore, an artisan would have been motivated to modify the dosage of the M. citrifolia in order to formulate a regimen that best achieves the desired results set forth in the reference. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of dosage amount would have been obvious at the time of applicant's invention.

Response to Arguments

Applicant's arguments filed November 15, 2004 have been fully considered but they are not persuasive. Applicant argues the reference does not teach of suggest the limitations in claims 29 and 30 because these claims depend from claim 27 which require a composition with M. citrifolia juice and puree. However, claims 29 and 30 do not depend from claim 27. Thus, the reference is still considered to properly teach claims 29 and 30 for the reasons discussed above.

9. Claims 1-28 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura (US Pat. No. 4,039,559) and Su (US Pat. Appl. No. 2002/0068102).

Su has three common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132

that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Nakamura teaches that carbon tetrachloride causes liver damage due to its ability to produce harmful free radicals. The reference uses a free radical scavenger to treat this damage (see column 4, lines 3-23). The reference does not specifically teach using M. citrifolia as the free radical scavenger. However, Su teaches a M. citrifolia composition that is a free radical scavenger (see paragraph [0014]). Su teaches that the free radical scavenging composition is formed of a mixture of M. citrifolia juice and puree (see paragraph 35). Therefore, based on the disclosures by the references, a person of ordinary skill in the art would reasonably expect that M. citrifolia would be able to treat liver damage caused by exposure to carbon tetrachloride because it is an antioxidant. Thus, an artisan of ordinary skill in the art would be motivated to use M. citrifolia to treat liver damage caused by exposure to carbon tetrachloride.

The references do not specifically teach administering the amounts of M. citrifolia claimed by applicant. The dosage of a pharmaceutical ingredient is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Su teaches that the base dosage of the M. citrifolia composition is one ounce and that an artisan can administer more than an ounce of the composition if needed to effectively reduce toxins (see paragraph 43). Therefore, an artisan would have been motivated to modify the dosage of the M. citrifolia in order to formulate a regimen that best achieves the desired results set forth in the references. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of dosage amount would have been obvious at the time of applicant's invention.

The references also do not specifically teach administering the composition in the forms claimed by applicant. These forms of administration are well known in the art to be acceptable means of administering a pharmaceutically active substance. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that administering the composition taught by the references in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to administer the composition taught by the references in the forms claimed by applicant.

Response to Arguments

Applicant's arguments filed November 15, 2004 have been fully considered but they are not persuasive. Applicant argues that the Su reference cannot be applied because the Su reference has inventors in common with the current application. However, the inventive entity between the current application and the Su reference is still different. Miam-Ying Wang is an inventor in the current application and is not an inventor for the Su application. Note that MPEP section 706.02(f) states "where there are joint inventors, only one inventor needs to be different for the inventive entities to be different and a rejection under 35 U.S.C. 102(e) is applicable even if there are some inventors in common between the application and the reference." Thus, the Su reference is not excluded because there is a different inventive entity between the current application and the Su reference.

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Coe Hoffman/
Primary Examiner, Art Unit 1655